

## **REMARKS/ARGUMENTS**

Claims 1-3, 40 and 41 are pending in the application. Claims 1-3, 40 and 41 are rejected. By the present amendment claims 1 and 40 are amended. Support for the amendment to claim 1 is found on application page 3, lines 17 and 18, and in Table II on pages 32 and 33 of the application. Support for the amendment to claim 40 is found on pages 24 and 25 of the application. The amendments add no new matter.

In view of the above-described amendments and the following remarks, reconsideration of claims 1-3, 40 and 41 is respectfully requested.

### Claim Rejections - 35 USC §102(b): Konishi and Smiraglia

The Patent Office rejected claims 1, 40 and 41 under 35 U.S.C. §102(b) as being anticipated by Konishi (Journal of Oral Pathology and Medicine, 1999, volume 28, pages 102-106), hereinafter “Konishi.” The Patent Office has also rejected claims 1-3, 40 and 41 under 35 U.S.C. §102(b) as being anticipated by Smiraglia, et. al. (Genomics, 1999, volume 58, pages 254-262), hereinafter “Smiraglia 1999.”

Amended claim 1 recites a method for identifying preferentially methylated CpG islands in malignant cells obtained from a tumor or neoplasm, wherein the tumor or neoplasm is from colon, glioma, non-squamous cell head and neck, lung, or non-medulloblastoma primitive neuroectodermal tumors (PNET). Amended claim 40 recites the method of claim 1 wherein the tumor or neoplasm from colon is stage I, II, III or IV as classified according to the American Joint Committee on Cancer staging and the tumor or neoplasm from PNET is supratentorial PNET.

Nowhere in either Konishi or Smiraglia are tumors or neoplasms from any of the tissues recited in Applicant’s amended claims 1 and 40 disclosed. Lacking such disclosure, neither Konishi nor Smiraglia anticipates Applicant’s amended claims 1 and 40. Claim 2 and 3 depend from amended claim 1, and claim 41 depends from claim 40, and are likewise not anticipated by Konishi or Smiraglia.

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Claim Rejections - 35 USC §103(a): Konishi in view of Plass

The Patent Office has rejected claims 2 and 3 under 35 U.S.C. §103(a) as being unpatentable over Konishi in view of Plass.

Claims 2 and 3 recite methods for identifying preferentially methylated CpG islands in malignant cells within a tumor or neoplasm, wherein the tumor or neoplasm is from colon, glioma, non-squamous cell head and neck, lung, or non-medulloblastoma primitive neuroectodermal tumors (PNET). The method of claim 2 comprises the steps of claim 1 and the step of determining the sequence of at least a portion of a diagnostic control cell restriction fragment used for identifying CpG islands. The method of claim 3 comprises the steps of claim 1 and the step of obtaining from a DNA library a clone which comprises a diagnostic control cell restriction fragment used for identifying CpG islands.

Konishi does not provide all of the steps recited in the methods of claims 2 and 3, and in particular, Konishi does not mention or suggest any of the tumors or neoplasms recited in independent claim 1 from which claims 2 and 3 depend. Plass does not provide what Konishi lacks, namely, Plass does teach or suggest any of the tumors or neoplasms recited in the instant claims. Accordingly, any combination of Konishi and Plass would not produce the methods as recited in Applicant's claims 2 and 3. Applicant submits that claims 2 and 3 are patentable over Konishi in view of Plass, and respectfully requests that the rejection of these claims be withdrawn.

Claim Rejections - 35 USC §103(a): Frühwald, Frühwald, Dai and Smiraglia in view of Plass

The Patent Office has rejected claims 1-3, 40 and 41 under 35 U.S.C. §103(a) as being unpatentable over the following: Frühwald (Genes, Chromosomes, & Cancer, September 13, 2000, volume 30, pages 38-47), hereinafter "Frühwald," in view of Plass; Frühwald (Abstract, Pediatric Oncology, June 2000), hereinafter "Frühwald Abstract," in view of Plass; Dai (Abstract, Stone Lab Meeting, September 2000), hereinafter "Dai Abstract," in view of Plass; and Smiraglia (Abstract, Gordon Research Conference, February 2000), hereinafter "Smiraglia Abstract," in view of Plass.

The publication dates of each of the primary references are less than one year prior to the filing date of the present application. Frühwald was published on September 13, 2000; the

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Fröhwald Abstract was published in June of 2000; the Dai Abstract was published in September of 2000; and the Smiraglia Abstract was published in February 2000. None of these references is a proper reference under § 102 (b). They are also not proper references under §102 (a). In support of this assertion, Applicant has attached a signed Rule 1.132 Declaration (pursuant to *In re Katz* USPQ 14 (CCPA 1982)), which explains that Dr. Plass is the sole inventor of the subject matter recited in the claims of the application, and that the other authors of the cited references are not inventors of the recited claims. Because none of these references is a proper reference under either subsection of §102, they are likewise not proper references under §103 (a). Accordingly, these references must be withdrawn. Because Plass does teach or suggest any of the tumors or neoplasms recited in the instant claims, Applicant submits that claims 1-3, 40 and 41 are not obvious, and respectfully requests that the rejection of these claims be withdrawn.

In view of the above-described amendments and remarks, it is submitted that claims 1-3, 40 and 41 are now in condition for allowance. Prompt notice of such allowance is respectfully requested.

Respectfully submitted,

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